UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE THREE TVT, TVT-O AND TVT-S CASES LISTED ON DEFENDANTS' EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE IN OPPOSITION TO ETHICON'S MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF ANNE WILSON

Plaintiffs submit the following memorandum of law in opposition to the "Motion to Exclude the Opinions and Testimony of Anne Wilson" filed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). Ethicon's Motion should be denied in its entirety, for the following reasons:

PRELIMINARY STATEMENT

Ms. Wilson adopted her Wave 1 TVT, TVT-O, and TVT-S reports for the Wave 3 cases. On August 25, 2015, the Court entered a Memorandum Opinion and Order [Doc. 2647] regarding the Wave 1 motion. In that Order the Court considered the issue of Ethicon's compliance with "design control and risk management standards," but reserved ruling on such matters because "the nuances of products liability law vary by state."[1] The Court found that "[e]ach standard must be assessed for its applicability to the safety questions at issue in this

[1] Doc. 2647 at 8.

litigation, consistent with state law."[2] Ethicon's renewed Memorandum against Ms. Wilson repeats it's same arguments from Wave 1 and 2. Ethicon also asks the Court to now rule on the "pure-*Daubert* arguments."[3] The Court has considered, but declined to rule on these issues at this time and nothing has changed since the Court's ruling.[4] No new reports or expert testimony have been provided by Ms. Wilson in this case.

As the Court has recognized, part of the *Daubert* analysis is whether the opinions fit the case—which requires an analysis of what is relevant under state law.[5] Ethicon's argument that this is a pure-*Daubert* "federal evidentiary" ruling is simply wrong. Ethicon's renewed attack on Ms. Wilson should be denied.

INTRODUCTION

Anne Wilson ("Ms. Wilson") is a Biomedical Engineer and Quality Assurance Consultant with nearly thirty (30) years of professional experience focusing exclusively on risk management, design controls, and quality system development for medical devices. Her career has focused on medical device development, and she also consults with medical device companies, helping them develop and maintain safe and effective medical devices, including help with retooling quality systems and risk assessments, which are issues that lie at the very heart of this case.[6] Her reports not only explain the industry standards in this regard, but also how Ethicon's design of its devices to treat Stress Urinary Incontinence ("SUI") failed to meet those standards.

Ethicon's Motion argues that Ms. Wilson's opinions are unreliable and, in some instances, incorrect. But in making these arguments, Ethicon ignores the evidentiary standards

[2] *Id*.
[3] Defs' Brf. at 2.
[4] *See* Doc. 2647.
[5] *See* Doc. 2647 at 8.
[6] *See* Ex. A, Wilson TVT-R Report.

of Federal Rule 702 and *Daubert* and the well-established principles of design control and risk assessment for medical devices.

Ms. Wilson bases her opinions on well-accepted principles of medical device design control and risk assessment, the documents produced in this litigation, as well as nearly thirty (30) years of experience in device design and risk assessment for medical devices.[7] And because Ms. Wilson's testimony is based on a sound methodology and will assist the jury's understanding of these issues, it should be allowed at trial. Ethicon's Motion to Exclude the Opinions and Testimony of Ms. Wilson should be denied.

STANDARD OF LAW

This Court is familiar with the standards for the admission of expert opinions. Pursuant to Federal Rule of Evidence 702, a witness who is qualified as an expert by knowledge, skill, experience, training, or education, may testify in the form of an opinion or otherwise if: (1) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (2) the testimony is based on sufficient facts or data; (3) the testimony is the product of reliable principles and methods; and (4) the expert has reliably applied the principles and methods to the facts of the case.[8]

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," means that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury.[9] In *Daubert*, the Supreme Court emphasized that "[v]igorous

[7] *See* Ex. A, Wilson TVT-R Report at 1-3.
[8] *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 668 (S.D. W. Va. 2014).
[9] *United States v. Dorsey*, 45 F. 3d 809, 813 (4th Cir. 1995).

cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."[10]

ARGUMENT

All of Ms. Wilson's opinions are relevant to the ultimate question of liability that the jury will decide in this case and her opinions are reliably based in the scientific method and relevant industry standards. Furthermore, Ms. Wilson's opinions are supported by the internal statements and conclusions of Ethicon researchers who have looked at the design of Ethicon's SUI devices and the defects inherent to them.

A. Ms. Wilson's opinions are reliable because they are based on a sound methodology applied to the facts of the case.

Ethicon's assertion that Ms. Wilson's opinions are unreliable because they are not based on a formal audit is without merit.[11] As this Court has previously noted, "[t]he Supreme Court has said that '[t]he objective of] the *Daubert* gatekeeping] requirement…is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'"[12] Ms. Wilson looks at a medical device manufacturer's risk management processes and identifies its strengths and weaknesses every day in her profession.[13]

As Ms. Wilson testified, she utilized the same methodology in preparing this case as she does in her everyday work:

> Q. So just to be clear, you have actually walked in the doors of medical device companies over the course of your career and performed the same analyses that you performed here, right, by looking at their risk management processes and identifying strengths and/or weaknesses?

[10] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993).
[11] Defs' Brf. at 3-5.
[12] *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851 2015 U.S. Dist. LEXIS 59047, at *33 (S.D. W. Va. May 6, 2015) (*quoting Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (U.S. 1999).
[13] Ex. B, Wilson Dep. 9/17/2015 at 417:23–419:4.

> A. Right. Those would be called -- like we call them gap analyses. They're not audits. So we would go in and do a gap analysis to look, gee, how did they, you know, comply with the standards? How did they respond over time? How do their documents, you know, look? And then we provide them a management report.
>
> Q. And when you did your expert report in this case, did you use the same methodologies that you use in your professional consulting for medical?
>
> A. Yeah. It's similar. And then I look—I consider my background and experience. I looked at—as an auditor, I looked at my consulting. And then I use all of those skills together to come up with a report, looking at the gaps and the opportunities for improvements.[14]

Moreover, Ms. Wilson explained at the outset of her expert reports that her methodology in this case is the same methodology she applies in her profession:

> In my profession as a Biomedical Engineer and Quality Assurance Consultant for medical device companies, I routinely analyze medical device manufacturers' risk management processes and identify their strengths and weaknesses. I regularly look at medical device companies' design and risk management documents, including design history files and FMEAs, and evaluate whether that documentation complies with industry standards and practices. For example, I routinely use root cause analysis methodologies to identify the deficiencies in medical device companies' processes such as design control, risk management, production issues, or CAPAs. These are the same analysis methods that I have performed in the course of my work in this case.[15]

Her expert reports provide the framework for her analysis and opinions in this case by listing and explaining the relevant standards for quality systems management as well as the accepted procedures for risk management within the medical device industry.[16] Moreover, Ms. Wilson's framework for her analysis in this case is her experience in the industry, generally accepted practices, and current standards.[17] As Ms. Wilson explained in her reports, the methodology she utilized in arriving at her opinions was to review Ethicon's design and risk documents within the framework of industry standards, and to evaluate whether Ethicon's design and risk management

[14] Ex. B, Wilson Dep. 9/17/2015 at 417:23–419:4.
[15] Ex. A, Wilson TVT-R Report, at 3; Ex. C, Wilson TVT-O Report, at 3; Ex. D, Wilson TVT-S Report, at 2-3.
[16] *See* Ex. A, Wilson TVT-R Report at 4–11.
[17] Ex. B, Wilson Dep. 9/17/2015 at 45:20–46:8.

of the TVT device complied with those industry standards.[18] There is nothing unreliable about her methodology, and her opinions should not be excluded.

B. Whether European authorities found that Ethicon complies with certain industry standards goes to the weight of the testimony, not the admissibility of that testimony.

Ethicon's contention that European authorities found that the TVT device complied with industry standards when it was first sold is not a proper basis for limiting or excluding Ms. Wilson's opinions in this case.[19] This is a contested issue with which Ms. Wilson disagrees. She has explained that, in her professional experience, whether or not a manufacturer has complied with certain industry standards cannot be based solely on certificates which state that a particular standard may have been met.[20] Ms. Wilson was able to explain why an audit, which only captures a "specific snapshot in time," is not relevant to whether a manufacturer has complied with industry standards.[21] Furthermore, the Court found in Wave 1 that whether "European and other international standards discussed had any bearing on the U.S. medical device industry" is unclear.[22]

Moreover, Ethicon's arguments conflict with the prior rulings of this Court. As this Court has found, it "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the

[18] *See* Ex. A, Wilson TVT-R Report at 13-14.
[19] *See* Defs' Brf. at 4.
[20] *See* Ex. B, Wilson Dep. 9/17/2015 at 115:16–116:6; 398:19–399:23; *see also* Ex. A, Wilson TVT-R Report at 14.
[21] Ex. B, Wilson Dep. 9/17/2015. at 39:7–20.
[22] Doc. 2647 at 7-8.

burden of proof.'"[23] As this Court noted in *Mathison*, a defendant may properly "cross-examine and impeach [an expert witness] at trial regarding any perceived oversights in her analysis."[24]

C. Ms. Wilson's opinions are not based on European regulatory standards.

Ethicon is also incorrect when it represents that Ms. Wilson's opinions are based on European regulatory standards.[25] At her deposition in the *Mullins* case, Ms. Wilson was explicit that her opinions were not based on *any* regulatory standards.[26] Instead, Ms. Wilson's opinions discuss the guidelines put forth by the International Organization for Standardization (ISO), including ISO 13485 and ISO 14971, which are universal guidelines relating to Quality Systems and Risk Management requirements for medical devices.[27]

This Court has previously allowed expert witnesses to testify regarding how guidelines set by the ISO apply to implantable medical devices, and part of Ms. Wilson's expertise lies in the same vein.[28] In accordance with this Court's prior rulings, "identifiable industry standards," such as ISO standards may provide a "reliable, objective basis for [expert] testimony."[29]

Additionally, in *Cisson*, this Court allowed the defendant to present evidence regarding its compliance with ISO standards.[30] Here, like in *Cisson*, evidence regarding whether or not a manufacturer's complied with ISO standards is relevant and admissible.

---

[23] *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972 2014 U.S. Dist. LEXIS 92316, at *4 (S.D. W. Va. July 8, 2014); *see also Pugh v. Louisville Ladder, Inc.*, 361 Fed. Appx. 448, 456 (4th Cir. 2010) (Any weaknesses in the underpinnings of an expert's opinion go to the opinion's weight, rather than its admissibility).
[24] *Mathison*, 2015 U.S. Dist. LEXIS 59047, at *55.
[25] *See* Defs' Brf. at 5-11.
[26] Ex. B, Wilson Dep. 9/17/2015 at 49:16–22 (Q. "Were any of the materials that you considered in forming this report, materials that would also be part of regulatory submissions in relation to these products? A. I did not look at any regulatory submission documents.").
[27] *See* Ex. A, Wilson TVT-R Report at 4–6; Ex. C, Wilson TVT-O Report at 4-6; Ex. D, Wilson TVT-S Report at 4-5.
[28] *See Mathison*, 2015 U.S. Dist. LEXIS 59047, at *98 (allowing Dr. Spiegelberg, a witness for Boston Scientific, to opine on ISO standards based on his "extensive experience in the field of medical device analysis and design.").
[29] *See id.* at *33 (quoting *Lasorsa v. Showboat: The Mardi Gras Casino*, No. 07-4321 2009 U.S. Dist. LEXIS 81948, at *13 (D.N.J. Sept. 9, 2009)).
[30] *Cisson v. C.R. Bard, Inc.*, No. 2:11-cv-00195 2013 U.S. Dist. LEXIS 149976, at *36 (S.D. W.V. Oct. 18, 2013) ("Similarly, evidence that Bard complied with standards set by the International Standards Organization (ISO)

Ethicon's argument that Ms. Wilson's mention of MIL-Q-9858A is irrelevant does not accurately reflect the substance of Ms. Wilson's reports.[31] Ms. Wilson mentions this standard as a historical example of an early QMS—she does not represent that it is directly applicable to modern medical device manufacturers.[32] Ethicon also suggests that ISO 9001 and EN 46001 are irrelevant.[33] But Ms. Wilson clearly explains the relevance of these standards in her reports.[34]

Ethicon's assertion that certain standards which Ms. Wilson relies upon must be retroactive to apply to these cases is similarly unfounded. Ms. Wilson explained in her reports that many of the standards she cites existed before the TVT-R device was first marketed in the United States.[35] Moreover, standards that were not adopted until after the TVT was first marketed in the United States are also relevant because they define how a manufacturer must update the design and risk assessment of a device by taking into account customer feedback of that device.[36] Ethicon's contention that certain standards must be retroactively applied solely focuses on the TVT-R device, and completely ignores Ethicon's TVT-O and TVT-S devices, which were not designed and marketed in the U.S. until after the dates when Ethicon concedes these standards were adopted.[37]

Ms. Wilson does not intend to retroactively apply industry standards; she is simply explaining how Ethicon's conduct in design and then continued risk assessment of the TVT device measures against standards and industry practices. Moreover, Ms. Wilson's opinions in

---

would not preclude the jury from awarding punitive damages. This evidence shows that Bard conducted biocompatibility and risk analysis in accordance with ISO standards.").

[31] Defs' Brf. at 6.

[32] *See* Ex. A, Wilson TVT-R Report at 4.

[33] Defs' Brf. at 7.

[34] *See* Ex. A, Wilson TVT-R Report at 5 (noting that these standards include requirements to "identify requirements that are related to the safety of the medical device…").

[35] *See id.*, Wilson TVT-R Report at 5 (noting that "ISO 13485 has defined the requirements for proper risk analysis in the medical device industry since 1996.").

[36] *See id.* at 5 (noting that ISO 13485 defines how to "handle complaints and product or system related CAPAs [corrective action and preventative actions] once a manufacturer becomes aware of feedback from any source.").

[37] *See* Defs' Brf. at 7-9.

this case are not based solely on industry standards—they are also based upon her professional knowledge and extensive experience in the medical device industry.[38]

Ethicon's assertion that the industry standards upon which Ms. Wilson relies are irrelevant because they have not been adopted by the FDA is also without merit.[39] Ms. Wilson intentionally excluded any consideration of, or reference to, the FDA in her reports.[40] Moreover, in *Mathison*, this Court rejected the suggestion that "the binding effect of industry standards dictates their reliability."[41] As this Court recognized in *Cisson*, "evidence of [a manufacturer's] compliance with ISO standards is relevant."[42] Here, like in *Cisson*, evidence of whether or not a manufacturer has complied with ISO standards is relevant to Plaintiffs' claims.

Finally, Ethicon's assertion that the industry standards upon which Ms. Wilson relies would cause unfair prejudice is without merit.[43] Ethicon attempts to equate ISO standards with FDA regulations and asserts that like FDA regulations, ISO standards could confuse and mislead the jury.[44] In *Mathison*, this Court considered and rejected a similar *Daubert* challenge to opinions of Plaintiff's expert witness, Dr. Peggy Pence:

> This argument misunderstands my concern with introducing FDA evidence. If I allowed BSC to express to the jury that its product complied with FDA regulations, the jury would then view the product with the gloss of federal-government endorsement, given that the product was cleared for market through the FDA's 510(k) process, which 'does not in any way denote official approval of the device.' 21 C.F.R. §807.97 (2012). GHTF standards, on the other hand, do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. And although the FDA appears to have had a limited role in the activities of GHTF, [] that role was not instrumental or definitive, and the work of the GHTF can be

[38] *See* Ex. A, Wilson TVT-R Report at 1-3.
[39] *See* Defs' Brf. at 9.
[40] Ex. B, Wilson Dep. 9/17/2015, at 181:9-14 ("I'm going to go back. My report, I exclusively -- I did not look at FDA because that was outside of the scope of my report. So I just want to make sure that you're aware of that."); *id.* at 393:22-394:22; Ex. F, Wilson Dep. 3/22/2016 at 31:17-23.
[41] *Mathison*, 2015 U.S. Dist. LEXIS 59047, at *43-44.
[42] *Cisson*, 2013 U.S. Dist. LEXIS 149976, at *36.
[43] *See* Defs' Brf. at 9-11.
[44] *Id*.

> described without reference to the FDA. Accordingly, I find BSC's argument without merit.[45]

Here, like in *Mathison*, Ms. Wilson's reliance upon industry standards does not run afoul of this Court's prior FDA rulings. Ms. Wilson's opinions in this case do not concern the FDA, but instead are focused on whether Ethicon's design of the TVT-R, TVT-O, and TVT-S meet identifiable industry standards.[46] Ms. Wilson has testified that she can offer these opinions at trial without reference to the FDA.[47] Indeed, this Court has previously allowed Dr. Spiegelberg to testify regarding medical device design and risk assessment based on ISO standards, as long as he did not mention in the FDA.[48]

D. Ms. Wilson's opinions have a reliable foundation in Ethicon's own documents.

Ethicon's assertion that Ms. Wilson's opinions should be excluded because she did not review certain documents is incorrect.[49] Ms. Wilson's reports and deposition testimony confirm that she has reviewed thousands of pages of Ethicon documents in forming her opinions in this case.[50] In her reports, Ms. Wilson explains that she "analyzed, reviewed, and relied upon" "Ethicon documents, including, but not limited to risk management documents, and quality assurance documents," as well as "[d]eposition transcripts of Ethicon employees."[51] Ms. Wilson further explained that she reviewed the entire design history files for the TVT-R, TVT-O, and TVT-S devices in connection with the design process and risks that were considered by Ethicon in the design of these devices.[52]

---

[45] *Mathison*, 2015 U.S. Dist. LEXIS 59047, at *43-46 (internal citations omitted).
[46] *See* Ex. A, Wilson TVT-R Report at 2-4.
[47] *See* Ex. B, Wilson Dep. 9/17/2015 at 393:22-394:22.
[48] *Mathison*, 2015 U.S. Dist. LEXIS 59047, at *98 ("[T]o the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so.").
[49] Defs' Brf. at 11-16.
[50] *See* Ex. B, Wilson Dep. 9/17/2015 318:13–24; 379:15–24; *see* Ex. A, Wilson TVT-R Report; Ex. C, Wilson TVT-O Report; Ex. D, Wilson TVT-S Report.
[51] Ex. A, Wilson TVT-R Report at 2.
[52] *Id.* at 15; Ex. C, TVT-O Report at 11; Ex. D, TVT-S Report at 12.

Whether Ms. Wilson's review of Ethicon documents included every document that Ethicon deems relevant is an issue that goes to weight of testimony and not the admissibility of that testimony, and is, therefore, a subject for cross-examination and impeachment. Indeed, as this Court has previously noted: "[a]n expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert*, so long as the expert has other 'sufficient facts or data' to support her opinion.[53] That is because, a defendant may properly "cross-examine and impeach [an expert witness] at trial regarding any perceived oversights in her analysis."[54]

Additionally, Ms. Wilson's opinions do not rest solely upon her review of Ethicon documents. Ms. Wilson's opinions are also reliable because they are based on her knowledge, skill, experience, training, and education as a biomedical engineer and quality assurance consultant.[55] Ms. Wilson's opinions in this case are built on her knowledge of the medical device industry and her nearly thirty (30) years of experience as a Biomedical Engineer in quality assurance.[56] Ms. Wilson holds certifications as a Certified Quality Auditor, Certified Quality Engineer, and Certified Quality Manager through the American Society for Quality, a Quality System Lead Auditor through Exemplar Global, and as a Registered Quality Assurance Professional in Good Laboratory Practice through the Society of Quality Assurance.[57] Ms. Wilson's work experience includes extensive experience with permanently implantable medical devices, including heart valves, artificial joints, shoulder anchors, cervical plates, and medical screws.[58] She founded and presides over a company that "consults with medical device

[53] *Mathison*, 2015 U.S. Dist. LEXIS 59047, at *55 (*citing* Fed. R. Evid. 702).
[54] *Id.*
[55] *See* Fed. R. Evid. 702 (noting that a witness may be "qualified as an expert by knowledge, skill, experience, training, or education.").
[56] *See* Ex. A, Wilson TVT-R Report at 2.
[57] *See id.* at 1.
[58] Ex. B, Wilson Dep. 9/17/2015, at 388:16–391:5.

manufacturers to develop and implement compliant solutions for their quality practices.[59] Ms. Wilson's background and credentials more than qualify her to testify regarding medical device industry risk assessment and quality standards and whether Ethicon's design of the TVT device complied with those practices and standards.

As the Fourth Circuit has recognized, the adequacy of an expert's knowledge goes to the weight of the testimony, not its admissibility, and thus presents a jury question.[60] Moreover, courts have recognized that "an expert may base his opinion on experience alone…"[61] For these reasons, Ethicon's motion must be denied.

E. Ms. Wilson does not misapply the industry standards.

Next, Ethicon wrongly asserts that Ms. Wilson's opinions should be excluded because she "misapplied" industry standards and that her opinions are unreliable and, in some instances, incorrect.[62] That is simply not so.

Ethicon asserts that Ms. Wilson misapplies ISO 14971 because she takes the position that any risk is unacceptable and that her definition of safety is different than the definition contained in ISO 14971.[63] But Ethicon mischaracterizes Ms. Wilson's opinions. In her reports, Ms. Wilson clearly explains that the ISO 14971 framework for risk is that: "[i]t is accepted that the concept of risk has two components: a) the probability occurrence of harm; [and] 2) the consequences of that harm, that is how severe it might be."[64] Ms. Wilson further explains that this concept of risk is one of the "basic concepts of patient safety."[65]

---

[59] Ex. A, Wilson TVT-R Report at 1.
[60] See *Humphries v. Mack Trucks, Inc.*, No. 98-1970 1999 U.S. App. LEXIS 25522, at *14 (4th Cir. Oct. 13, 1999).
[61] *Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 368 (S.D.N.Y. 2003) ("[T]he fact that an expert 'may have neglected to perform some 'essential' tests or measurements…goes to the weight of his testimony, not its admissibility") (*quoting Lappe v. Am. Honda Motor Co.*, 857 F. Supp. 222, 228 (N.D.N.Y. 1994).
[62] Defs' Brf. at 19-24.
[63] Defs' Brf. at 19.
[64] Ex. A, Wilson TVT-R Report at 6.
[65] *Id.*

Ethicon's argument that Ms. Wilson's opinions failed to take into account whether or not a medical device was "state of the art" is also without merit.[66] The weighing of contrary evidence regarding the safety and design of Ethicon's SUI devices is for the finder of fact to determine.[67]

Likewise, Ethicon's argument that Ms. Wilson seeks to retroactively apply standards to Medscand's design documentation is unfounded.[68] Ms. Wilson does not intend to retroactively apply standards; she is simply explaining how Ethicon's conduct in the design and continued risk assessment of Ethicon's SUI devices measures against standards and industry practices existing at the time of that conduct. For example, Ms. Wilson testified in *Mullins* that she has reviewed an audit of Medscand by Ethicon which highlighted non-conformances with design documentation requirements.[69] Ms. Wilson seeks to explain how non-conformances such as this are important to how a manufacturer's risk assessment functions.

Ms. Wilson explains in her reports that the missing documentation relating to the design of the TVT-R device is a violation of medical device industry practices.[70] Ethicon cavalierly asserts that Ms. Wilson's criticism in this regard is unsupported because, "for obvious reasons," Ethicon would not have these documents for a device they purchased for a different manufacturer—but Ethicon offers no support for its position that such documentation was not available to it.[71]

---

[66] Defs' Brf. at 20.
[67] *See Daubert*, 509 U.S. at 596 ("vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking expert testimony.").
[68] Defs' Brf. at 20-21.
[69] Ex. B, Wilson Dep. 9/17/2015 at 64:4-18.
[70] *See* Ex. A, Wilson TVT-R Report at 15.
[71] Defs' Brf. at 21.

Ethicon also takes issue with Ms. Wilson's discussion of its "design history file remediation."[72] Here, Ethicon accuses Ms. Wilson of deliberately misquoting a document "in order to create a false impression" and "deceitfully" using this document.[73] Ms. Wilson's mention of this document serves only to provide historical information regarding when Ethicon took over the design control activities from Medscand.[74] Ms. Wilson discussed the significance of Ethicon taking over the design control of the TVT-R product from Medscand at her deposition.[75] Moreover, if Ms. Wilson is wrong about what the document says, that is an issue for cross examination.

And it is Ethicon, not Ms. Wilson, who seeks to "create a false impression" when it argues that Ms. Wilson "applies the wrong standard" in her analysis of Ethicon's 2001 dFMEA.[76] Indeed, Ethicon takes statements in Ms. Wilson's reports and deposition out of context and attempts to confuse the issues in this case. Ms. Wilson clearly explained in her reports which Ethicon procedures apply to Ethicon's dFMEA.[77] Moreover, Ethicon ignores controlling legal precedent by even raising this argument. As this Court has found, it "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'"[78]

---

[72] Defs' Brf. at 22.
[73] *Id*.
[74] Ex. A, Wilson TVT-R Report at 15.
[75] Ex. F, Wilson Dep. 3/22/2016 at 111:10-24. One of Ethicon's expert witnesses in this case admitted at her deposition that having typos in her report "doesn't alter the quality of the opinions." Ex. E, Deposition of Elaine Duncan, 10/6/2015, at 62:2-6.
[76] Defs' Brf. at 22-23.
[77] Ex. A, Wilson TVT-R Report at 12-13.
[78] *Edwards*, 2014 U.S. Dist. LEXIS 92316, at *4; *see also Mathison*, 2015 U.S. Dist. LEXIS 59047, at *55 (noting that perceived oversights in an expert's analysis are proper fodder for cross examination and impeachment at trial)

F. Ms. Wilson is not offering medical opinions.

Ethicon also mischaracterizes Ms. Wilson's reports by claiming they consist of medical opinions.[79] In truth, not one of Ms. Wilson's opinions is a medical conclusion. Instead, what Ethicon cites as "medical opinions" is factual background for Ms. Wilson's risk assessment opinions.[80] Indeed, Ms. Wilson clearly explains this point in her reports: "The clinical implications of each of these complaint categories are discussed by medical physicians in other expert reports submitted in this litigation. I offer no opinions on the clinical implications or the frequency of any of those complications throughout the population in this report."[81] Simply put, Ms. Wilson's opinions as to whether Ethicon's design controls and risk assessment complied with industry standards applicable to medical devices are well-qualified and reliable—and they are not "medical opinions."

G. Ms. Wilson's opinions regarding warning information in the risk management process are based on her experience.

Product warnings that relate to risk assessment are relevant and within Ms. Wilson's expertise.[82] Ethicon attacks Ms. Wilson's ability to offer any warnings testimony on the grounds that she is not a physician.[83] However, Ethicon cites to no authority requiring that an expert be a physician, as opposed to a biomedical engineer like Ms. Wilson, to testify regarding risk assessment practices relating to warnings. Moreover, Ethicon failed to verify at Ms. Wilson's deposition whether her professional experience includes IFUs or product warnings. Ms. Wilson has clearly explained in her reports how warnings are a fundamental part of the risk management

[79] Defs' Brf. at 24-25.
[80] *See* Ex. A, Wilson TVT-R Report at 24–31.
[81] *See id.* at 24.
[82] *See id.* at 11 (noting that "known or knowable risks will be identified, warned about, or mitigated" as part of the risk management process).
[83] Defs' Brf. at 24.

of a medical device.[84] As such, Ms. Wilson should be allowed to offer opinions regarding product warnings as a fundamental part of the risk management process in the medical device industry.

CONCLUSION

For the reasons stated herein, Plaintiffs respectfully request that the Court DENY Ethicon's Motion to Exclude the Testimony of Anne Wilson in its entirety.

Dated: October 11, 2016

Respectfully submitted,

s/ Edward A. Wallace
Edward A. Wallace
Mark R. Miller
Timothy E. Jackson
Wexler Wallace LLP
55 W Monroe Street, Suite 3300
Chicago, Illinois 60603
(312) 346-2222
(312) 346-0022
eaw@wexlerwallace.com
mrm@wexlerwallace.com
tej@wexlerwallace.com

Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com

Thomas P. Cartmell
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
(816) 701-1102
(816) 531-2372 (fax)
tcartmell@wcllp.com

[84] *See* Ex. A, Wilson TVT-R Report at 8 ("[w]arnings and training are the least effective means of minimizing risks of a product and should only be used as a last opinion").

CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace_____